

**SPECIALIZED CENTERS OF RESEARCH (SCORs)  
on Sex and Gender Factors Affecting Women's Health**

**Office of Research on Women's Health**

**I. INTRODUCTION**

The Office of Research on Women's Health (ORWH) has issued RFA OD-06-003 - Specialized Centers of Interdisciplinary Research (SCOR) on Sex and Gender Factors Affecting Women's Health - to promote institutional interdisciplinary research in an area important to women's health. **The RFA lists the research objectives, eligibility information, general application and submission, and detailed review requirements and should be used for that information.**

These guidelines are intended only to aid in assembling the application in a uniform manner to make the review process more favorable for the applicant. A uniform presentation makes it easier for reviewers to use and also serves as a checklist for the applicant institution preparing the application.

**The RFA label available in the application package must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.**

NOTE:NIH REQUIRES THAT APPLICATIONS SUBMITTED IN RESPONSE TO A RFA MUST ARRIVE NO LATER THAN THE APPLICATION RECEIPT DATE: **SEPTEMBER 14, 2006**

All appendix material must be clearly marked with the Center Director and the appropriate project or core.

**II. SUGGESTED CONTENT ORDER FOR APPLICATIONS**

**A. Face page, Abstract Page, Table of Contents**

PHS 398 is required for all applications. Each budget unit (project or core) should be written in the style and within the page limitation described in the PHS 398 instruction kit. To aid in the review of these applications, the applicant should assemble the component units following the format described below.

**Face Page** of Form PHS 398 . Complete all items on the face page as directed. In the title block, item 1, put your descriptive title. Mark item 2 "yes" and write in the RFA code, OD-06-003, (as listed in the NIH Guide to Grants and Contracts announcement) and "ORWH: SCOR on Sex and Gender Factors Affecting Women's Health" for the RFA title.

**Page 2:** Describe the **overall** proposed program indicating the goals and objectives of the projects.

**Table of Contents:** Discard this page from Form PHS 398 and write a Table of Contents appropriate for the SCOR grant application. This is paginated to follow the list of Key

Personnel. **Do not use letters (e.g. 4a, 4b, 4c, etc.)** The Table of Contents should specifically list the locations of the overall budgets, biographic sketches and various narrative sections. Also, list projects and cores for which funding is sought with the title and Principal Investigator. **INCLUDE THE NUMBER AND TITLE FOR EACH PROJECT AND CORE**, for example, Project 1: Genetics factors underlying sex differences in metabolism. PI: John Doe, M.D.; Core A: Administrative Core, PI: John Doe, M.D.

## **B. Budgets and Other Supporting Forms**

**Budget:** Justify and document all costs for current and future years throughout at the level of the individual component budgets.

The **overall** Center budget, "Summary Center Budget," is to be presented first using PHS Form 398 page 4 entitled "Detailed Budget for First 12-Month Period" using a composite summarizing all individual budgets (that is, under personnel, total the personnel costs for ALL components and continue for the other budget items.) No details need be given for the individual categories.

To provide budget information in a format that is clear to reviewers and therefore provides the most positive review possible, presentation of a consolidated budget for the first 12 months in a tabular form such as the sample shown as Exhibit I is suggested.

Page 5 of PHS Form 398, "Budget Estimates for All Years of Support Requested Direct Costs Only", should then follow, a composite summarizing all individual budgets (that is, under personnel, total the personnel costs for ALL components and continue for the other budget items.) For the purpose of establishing future year budget requests, the applicant should use cost escalations of 3% or less.

Both first 12 month and 5 year **individual** budgets, should be included *in the sections for each project and core*. Details and justifications for all budget items must be part of the individual budgets. Read carefully pages 10 - 14 of the Instructions for PHS 398 on how to prepare budget pages and justifications.

Note that this grant mechanism is not intended for the acquisition of costly equipment which should be funded through other sources. Under unusual circumstances, where costly items of equipment are requested, the application must document available equipment within the institution and provide clear justification.

**Biographical Sketches:** Biographical sketches are required for all professional level personnel who are listed with a percent effort (including consultants) in the SCOR application. The forms found in Form PHS 398 should be used. After the budget pages, put the PI sketch first, followed by the other individual sketches in alphabetical order. These pages should not be duplicated in the individual component projects and cores.

## **C. Overall Research Plan, Leadership & Resources**

Using continuation pages, substitute the following for the Research Plan instructions of Form PHS 398. **Note - this section is intended to be read by all reviewers, even if they are not assigned to projects within this application. Therefore it is important to provide a succinct, yet comprehensive overall research plan.**

The section on Overall Research Plan, Leadership and Resources should not exceed 25 pages.

### **1. Program Introduction and Statement of Objectives**

State the research theme that is the focus of the application. Describe the rationale for the proposed research program, and explain the strategy for achieving the objectives of the overall program, how each project and core unit relates to the strategy, and how the projects and cores relate to one another. Describe which are the clinical research projects and the rationale for each within the SCOR theme. Describe the nature of the interdisciplinary team and approach.

It is important to indicate prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, and to predict the anticipated unique advantages that would be gained by the research within the proposed SCOR.

### **2. SCOR Leadership**

The emphasis in this section should be on the qualification of the SCOR leadership. Describe the qualifications of the SCOR Director to lead the program.

### **3. Environment and Resources**

Briefly describe the features of the institutional environment that are or would be relevant to the effective implementation of the proposed program. As appropriate, describe available resources, such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consultative resources.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

### **4. Competing Continuation Applications: Additional Material Required**

All applications for competitive renewal must provide information documenting the impact of the research from the original application. See the RFA for the review criteria to be addressed.

## **D. Presentation of Budgeted Components**

## 1. Projects

Using Form PHS 398, name and number each project sequentially so that it can be readily distinguished from other projects in the program. Each research project should be clearly identified by the same title as that provided in the Table of Contents. The project should begin with the abstract and budget pages and should follow the instructions for Form PHS 398. Describe each section in the same detail and format as required for a regular research grant application so that the scientific merit can be judged on the basis of the written proposal. Adhere to the page restrictions indicated in the instructions for Form PHS 398. **Begin each project with a short section that clearly states how that project contributes to the theme of the SCOR as a whole. If it is a clinical research project, describe the rationale of including it as a clinical research project within the theme of the SCOR.**

The budget for each research project should reflect the instructions for Form PHS 398. A detailed budget is required for the first year; budget estimates are required for all subsequent years of support. Explicit and detailed budget justifications must be included for all years. Budget pages must be labeled so that they can be readily associated with the particular projects to which they apply. The project principal investigator should devote at least 15 percent effort to the research.

In the project, include the sections for both animal and human subjects. If there are none, so state; otherwise carefully follow the detailed instructions the PHS 398 guidelines.

## 2. Research Cores

Each core must be written using Grant Application Form PHS 398. Name and assign a letter designation to each unit. An abstract should be written for each core.

A core may be a unit designed just for the SCOR projects or may be an institutional core unit. However, funds may only be requested for SCOR use, and the core must serve a minimum of two projects within the SCOR, with no project dominating use of the core. The core principal investigator should devote at least 15 percent effort to the core.

Describe the core unit and the various services it would provide. (For suggestions on presenting information, see Exhibits II and III.) The justification for the core must include the value added by having services provided through the core rather than by the individual projects. Describe the personnel, facilities, management and any special arrangements such as cooperation with other established cores. The techniques to be used and the quality control procedures should be documented and justified. Indicate which core services each project would utilize. Include the sections for both animal and human subjects. If there are none, so state; otherwise carefully follow the detailed instructions the PHS 398 guidelines. Each core using human

subjects must include a discussion of the composition of women and minority subjects and the inclusion of children.

### **3. Administrative Core**

The purpose of a SCOR is to expedite development and application of new knowledge of specific importance to diseases. The Administrative Core is responsible for the overall administration of the SCOR. Describe in detail, and by diagram if appropriate, the chain of responsibility for decision-making and administration. Include to whom the program director reports and the administrative structure as it relates to the investigators responsible for the research projects and core units. If advisory groups will be used, indicate their specific functions and to whom they report.

The administrative core must include a clinical investigator who is responsible for the translation of basic research to clinical research to assure a mutually supportive interaction between scientists conducting basic research and those performing clinical investigation. The qualifications of the clinical investigator and the plan to promote patient based research should be described.

The SCOR director is expected to make a commitment of at least 10 percent effort to the overall administration of the program plus 15 percent effort as a principal investigator of a SCOR project. Administrative support personnel may be budgeted in at no more than one full time equivalent (FTE) which may be divided among one or more positions. This FTE must be fully justified.

Note that the director and co-director should budget for an annual two day meeting in Bethesda, MD with ORWH staff.

Indicate who would be responsible for assisting the program director with the day-to-day administrative details, program coordination, and planning and evaluation of the program, and who would be in charge in the absence of the director. Describe procedures for appointing a replacement for the program director if the need should arise.

**EXHIBIT I *SAMPLE OF SUGGESTED FORMAT***

**CONSOLIDATED BUDGET FOR 1ST YEAR OF REQUESTED SUPPORT**

BUDGET CATEGORY	Project 1	Project 2	Project 3	Core A	Core B	Core C	TOTAL
Personnel							
Consultant Costs							
Equipment							
Supplies							
Domestic Travel							
Foreign Travel							
Patient Care Costs							
Alteration and Renovation							
Contractual Costs							
Other Expenses							
<b>Total Direct Costs</b>							

**EXHIBIT II *SAMPLE OF SUGGESTED FORMAT***  
**USE OF CORE FACILITIES**

CORE: *NAME*

Determinations/Services Rendered

- A.
- B.

<u>Users</u>	<u>Funded Projects with Identifying Number</u>	<u>Period of Core Use</u>	<u>Determinations/Services</u>	<u>Estimated Use and Comments</u>
1.				
2.				
3.				

EXAMPLE	EXAMPLE	EXAMPLE	EXAMPLE
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CORE: Cell Culture

Determination/Services Rendered

- A. Fibroblast Cell Cultures
- B. Cell Isolations
- C. Special Media Preparation
- D. Isotopic Labeling

<u>Users</u>	<u>Funded Projects with Identifying Number</u>	<u>Period of Core Use</u>	<u>Determinations/Services</u>				<u>Estimated Use and Comments</u>
			<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>	
J.F. Smith	R01AR42846-02	3/06 - 2/09		X	X		B. 4 per mo C. 15 per mo
S.R. Jones	K01AR41654-04	6/06 - 5/09	X			X	A. 2 per mo D. 6 per mo

### **EXHIBIT III SAMPLE OF SUGGESTED INFORMATION FOR A CORE**

Sample of information useful to reviewers in evaluating a core. This example was developed for a tissue acquisition core.

- I. What types of samples are needed?
  - A. Diseases
  - B. Numbers of samples
  - C. Source of samples
  - D. Age
  - E. Sex
  - F. Tissues
- II. What patient population is available? Is it sufficient?
- III. What tissues are potentially available?
  - A. Neonatal foreskins
  - B. Surgical specimens of normal skin
- IV. Ability to communicate needs with clinicians:
  - A. Is there regular contact between the core director and clinicians? A Ph.D. core director may be less desirable because of lack of patient contact and lack of regular contact with clinicians, especially clinicians not part of the research effort.
  - B. How will needs be communicated to clinicians, especially residents and clinicians not engaged in research?
- V. Ability to harvest tissues and transport tissues and supplies:
  - A. Who will harvest tissues? (Same clinician who sees patients in a busy clinical setting; Residents; designated member of the tissue acquisition core)
  - B. Will these be biopsies required for patient care or will the biopsies be only for research purposes? Is it feasible to expect additional biopsies to be performed in a busy clinic?
  - C. How will the clinicians obtain needed special supplies required for harvesting certain tissues (flash freezing or special fixatives for EM)? Who will either transport these supplies to the clinic or maintain a stock in the clinic?
  - D. Who will transport tissues to the core? This is especially critical with frozen tissues and tissues requiring viability.
- VI. Proof of previous ability to obtain similar samples:
  - A. Publications and preliminary data demonstrating success at sample collection.
  - B. Was it necessary to pay donors?

Justify budget and required technician effort by estimating volume of samples and slides.